



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,844	06/23/2003	Manne Satyanarayana Reddy	BULK 3.0-018	9550
45776 7590 05/24/2007 DR. REDDY'S LABORATORIES, INC. 200 SOMERSET CORPORATE BLVD SEVENTH FLOOR, BRIDGEWATER, NJ 08807-2862			EXAMINER WARD, PAUL V	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 05/24/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/601,844	<b>Applicant(s)</b> REDDY ET AL.	
	<b>Examiner</b> PAUL V. WARD	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

1. **STATUS:** The rejection of claims 1-18 under 35 U.S.C. 102, 103 and 112, set forth in the Office action dated November 17, 2006 has been maintained for the reasons of record for the reasons set forth herein.

#### *Priority*

2. Claim for foreign priority under 35 U.S.C. § 119 is acknowledged.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim refers to a Figure. Correction is required.

The term "substantially" in claims 2 and 10 is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

#### ***Response to Arguments regarding***

#### ***Claim Rejections - 35 USC § 102 and 35 USC § 103***

4. Applicant's arguments filed January 17, 2007 have been fully considered but they are not persuasive.

Applicant claims amorphous levocetirizine dihydrochloride, amorphous levocetirizine dihydrochloride free of crystalline forms of cetirizine dihydrochloride, and

compositions comprising the levocetirizine dihydrochloride. Additionally, Applicant claims compositions of levocetirizine dihydrochloride containing a moisture content ranging from about 0.3 % to 12% using the KF method.

Tang teaches the exact amorphous levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 311, Fig. 1 pg. 311, and Figures 2-3 on pg. 312). Since Tang teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Pflum teaches the exact amorphous levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 110, Fig. 1 pg. 110, and Tables 2-3 on pg. 111 and left col.). Additionally, on page 111, left hand column, and on page 112, right hand column (last paragraph), Pflum teaches that the levocetirizine contain yields of 79% and 99%. Since Pflum teaches the exact compounds, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Van de Venne teaches compositions comprising levocetirizine dihydrochloride with one or more pharmaceutically acceptable excipients, and falls within the range of Applicant's compounds. (See Abstract, col. 3 lines 45-60, col. 5, lines 10-55, and Table in col. 6). Since Van de Venne teaches the exact compositions, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

### ***Claim Rejections - 35 USC § 103***

5. Applicant claims compositions comprising levocetirizine dihydrochloride containing a moisture content ranging from about 0.3 % to 12% using the KF method.

Van de Venne teaches compositions comprising levocetirizine dihydrochloride (See Abstract and columns 3-6). The claims differ from the reference by reciting the composition containing a moisture content.

Thus, Van de Venne does not teach Applicant claims in the same format as claimed by applicant, however, one skilled in the art would find the differences in the teaching to be negligible. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Van de Venne to obtain the compositions as claimed in the instant application. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar properties. Therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for levocetirizine compositions. See *In re Payne*, 203 USPQ 245 (CCPA 1979). Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

Applicant argues that the prior art does not disclose "amorphous" levocetirizine dihydrochlorides.

The amorphous form is an obvious variation, which one is motivated to obtain because of the expected solubility advantage. Note this from the conclusion of Hancock, Pharm. Res. 17(4) 397 (2000): "Amorphous pharmaceuticals are markedly more soluble than their crystalline counterparts...Based on a comparison with polymorphic crystal forms of drug compounds the clinical relevance of solubility increases for amorphous drug forms is likely to be significant, even in systems which are only partially amorphous.

Thus, Applicant arguments are not persuasive. Therefore, the rejection of claims 1-18 under 35 U.S.C. 102, 103 and 112, set forth in the Office action dated November 17, 2006 has been maintained for the reasons of record for the reasons set forth herein.

***Conclusion***

Claims 1-18 are pending. Claims 1-18 are rejected. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V. WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in cursive script, appearing to read "Bruck Kifle", is positioned above a horizontal line.

Bruck Kifle  
Primary Patent Examiner  
Technology Center 1600